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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,613	02/10/2004	Tomoko Takeshita	HIRA.0141	1668

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EXAMINER

GALVEZ, JAMES JASON

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 07/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/774,613

Applicant(s)

TAKESHITA ET AL.

Examiner

J. Jason Galvez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 7-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

The amendment filed 5/4/2005 has been made of record. Claims 1-12 are pending. Claims 7-12 are drawn to non-elected subject matter. Accordingly, claims 1-6 are under examination. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Objections/Rejections: Withdrawn

Oath/Declaration

Objection to the oath/declaration has been withdrawn.

Drawings

Objection to the drawings, particularly Figure 7, has been withdrawn in response to amendments submitted by Applicant.

Claim Objections

Objection of claims 2, 5 and 6 has been withdrawn in response to amendments submitted by Applicant.

Claim Rejections - 35 USC § 112, 1st paragraph

Rejection of claims 1-6 under 35 U.S.C. § 112, first paragraph, for not meeting the full scope of the enablement requirements has been withdrawn in response to

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arguments presented by Applicant and upon further consideration.

Rejection of claims 1-6 under 35 U.S.C. § 112, first paragraph, for not meeting the written description requirements has been withdrawn in response to arguments presented by Applicant and upon further consideration.

5

Claim Rejections - 35 USC § 112, 2nd paragraph

Rejection of claims 2 and 6 under 35 U.S.C. § 112, 2nd paragraph, for being indefinite regarding the recitation of "N-terminal side" and "C-terminal side" has been withdrawn in response to amendments to claims.

10 Rejection of claims 5 and 6 under 35 U.S.C. § 112, 2nd paragraph, for being indefinite regarding the recitation of "group", in reference to cells, has been withdrawn in response to amendments to claims.

Objections/Rejections: Maintained/New Grounds

15

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

20

Claims 1-6 are newly rejected under 35 U.S.C. 101 because the claimed invention is drawn to cells comprising orphan GPCRs and methods of making the same. The claimed cells comprising orphan GPCRs and methods of making the same are not supported by either a specific and substantial asserted utility or a well-established utility.

A specific and substantial utility is one that is particular to the subject matter claimed and that identifies a "real world" use for the claimed invention. See *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966):

5 The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

10 Although the instant disclosure does not specifically recite orphan GPCRs the claims and the specification read on these orphan receptors. Applicant discusses using known GPCRs, but a method of screening for ligands of known GPCRs would offer no benefit over the manner in which such ligands are currently screened. Therefore the instant invention is interpreted to be drawn to cells and methods of making cells comprising orphan GPCRs. As discussed in the previous office action, orphan GPCRs
15 have no known function by definition (see office action mail date: 2/4/2005). Since orphan GPCRs have no known function, cells comprising orphan GPCRs and methods of making said cells would also have no known function. Therefore, uses such as a screening method for a ligand of a GPCR (p. 6) is useful for research purposes to further characterize the GPCR as it reads on orphan GPCRs. No "specific benefit exists
20 in currently available form", only an invention for experimentation to further characterize the orphan GPCR. Furthermore, the asserted utility of screening methods using the claimed cells comprising GPCRs, which include orphan GPCRs, is not substantial. A substantial utility, by definition, is a utility that defines "real world" use, and a utility that requires or constitutes carrying out further research to identify or reasonably confirm a

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"real world" context of use does not have a substantial utility. In the instant case, the methods are directed to, in part as they read on orphan GPCRs, characterization of receptors with unknown functions and unknown ligands. As such, the claimed invention is not considered substantial.

5 The invention also lacks a well-established utility. A well-established utility is a specific, substantial, and credible utility that is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material. The claims and the specification read on cells comprising orphan GPCRs and methods of making the same. Since orphan GPCRs have no known function or ligand, cells comprising orphan
10 GPCRs would not be well-established. Accordingly, cells comprising orphan GPCRs and methods of making the same lack a well-established utility.

 It is noted Applicant alleges the claimed invention is not directed to orphan GPCRs. Applicant states, "...the GPCRs recited in the instant claims are those that couple with specific G-proteins, i.e., G-proteins other than G_q subtype G-proteins. Such
15 GPCRs and G-proteins other than G_q subtype G-proteins are already known to one skilled in the art".

 Arguments presented by Applicant are not persuasive. Orphan GPCRs could or could not be coupled to G-proteins other than G_q subtype G-proteins. Orphan GPCRs have no restriction on the G-proteins to which they are coupled. The only certainty
20 pertaining to orphan GPCRs is that these receptors have no known function and ligand. As such, the claims and the specification do not exclude orphan GPCRs since these

receptors can, and unless shown otherwise do, couple to G-proteins other than G_q subtype G-proteins.

Claim Rejections - 35 USC § 112

5 Claims 1-6 are newly rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility for the reasons set forth above, a person of ordinary skill in the art would not know how to use the claimed invention.

10 Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to cells and methods of
15 making cells comprising GPCRs "that couple with G-proteins other than G_q subtype G-proteins". There is no support in the specification for this exclusionary statement. Applicant does not explicitly or implicitly limit the GPCRs to those "that couple with G-proteins other than G_q subtype G-proteins". This is a new matter rejection.

20 ***Claim Rejections - 35 USC § 102***

Rejection of claims 1, 2, 5 and 6 as being anticipated by Nakamura *et al.* under 35 U.S.C. § 102(b) is maintained for the reasons of record (see office action mail date: 2/4/2005). Applicant states on the record that Nakamura *et al.* teach transfected cells

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with specific chimeric G_q constructs together the GPCR mGluR1. However, Applicant argues amendment of claims 1 and 5, which read on GPCRs that are coupled to G-proteins other than G_q, separates the instant invention from the prior art cited. Applicant states, "Nakamura fails to teach or disclose cells transfected with chimeric G_q subtype G-proteins together with GPCRs that couple with G-proteins other than G_q subtype G-proteins". Therefore it is the position of Applicant that Nakamura *et al.* do not meet all the limitations of the claims.

Arguments presented by Applicant have been considered, but have not been found persuasive. Based on arguments set forth by Applicant, traversal of the instant rejection is that Nakamura *et al.* does not teach "...cells transfected with chimeric G_q subtype G-proteins together with GPCRs that couple with G-proteins other than G_q subtype G-proteins". Applicant argues this from the standpoint that mGluR1 only interacts with G_q subtype G-proteins. However, Hermans *et al.* teach mGlu1a receptors, a member of mGluR1 receptors, can interact not only with G_q, but also other G-protein subtypes such as G_i, G_o and G_s (Biochem J. 2001, Vol. 359(Pt 3): pp. 465-484, esp. p. 472: Figure 3). Therefore, Nakamura *et al.* clearly teach cells transfected with a chimeric G_q subtype comprising G_{11α} and G_{14α} and a GPCR that couples to G-proteins other than G_q.

Claim Rejections - 35 USC § 103

Rejection of claims 3 and 4 as being unpatentable over Nakamura *et al.* and MPEP § 2411 under 35 U.S.C. § 103 (a) is maintained for the reasons of record (see

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office action mail date: 2/4/2005). Applicant argues Nakamura *et al.* does not teach limitations of claims 3 and 4 as set forth in arguments summarized under 35 U.S.C. 102. Specifically, Applicant argues there is no motivation in Nakamura *et al.* or the knowledge generally available to the skilled artisan to arrive at the instant invention.

5 Arguments presented by Applicant have been considered, but have not been found persuasive. As discussed above Nakamura *et al.* clearly teach cells transfected with a chimeric G_q subtype comprising G_{11α} and G_{14α} and a GPCR that couples to G-proteins other than G_q since mGluR1 receptors can be coupled to G-protein subtypes other than G_q. As for motivation, the transfection conditions would be routinely
10 optimized by the skilled artisan using general knowledge of the skilled artisan in an effort to maximum transfection efficiency and yield taking into consideration the transfection time, concentration, and/or ratio of genes.

Conclusion

15 NO CLAIMS ALLOWED.

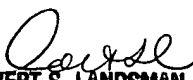
Any inquiry concerning this communication or earlier communications from the examiner should be directed to **J. Jason Galvez, Ph.D.** whose telephone number is **571-272-2935**. The examiner can normally be reached Monday through Friday 9 AM to 5 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's
20 supervisor, **Brenda Brumback, Ph.D.** can be reached at **571-272-0961**.

The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**. Information regarding the status of an application may be

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obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

10 JJG
7/19/2005


ROBERT S. LANDSMAN, PH.D.
PRIMARY EXAMINER